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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,843,901

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,843,901, which claims the human drug product Plenaxis® (abarelix) and a pharmaceutical composition of Plenaxis® (abarelix), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 725 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 725 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of September 29, 2006, (71 Fed. Reg. 57545), would be 1,450 days. Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (1,487 - 745) + 1,079
	=	1,450 days (4.0 years)

Since the regulatory review period began November 17, 1996, before the patent issued (December 1, 1998), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From November 17, 1996, to and including December 1, 1998, is 745 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,450 days, would extend the patent from December 1, 2015 to November 20, 2019, which is beyond the 14-year limit (the approval date is November 25, 2003, thus the 14 year limit is November 25, 2017). The period of extension is thus limited to November 25, 2017, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, December 1, 2015, to and including November 25, 2017, or 725 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,843,901
Granted:	December 1, 1998
Original Expiration Date[1]:	December 1, 2015
Applicant:	Roger W. Roeske
Owner of Record:	Advanced Research and Technology Institute
Title:	LHRH Antagonist Peptides
Product Trade Name:	Plenaxis® (abarelix)
Term Extended:	725 days
Expiration Date of Extension:	November 25, 2017

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: Plenaxis® (abarelix)
FDA Docket No.: 2005E-0253

[1]Subject to the provisions of 35 U.S.C. § 41(b).